REMARKS

Reconsideration and withdrawal of the rejections of the Office Action are respectfully requested in view of the remarks herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1, 5, 6, 10-22, 30 and 31 are currently pending. Claims 1, 5, 6 and 30 have been amended, claims 2-4 and 7-9 have been cancelled, and new claim 31 has been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is respectfully submitted that the claims herewith and as previously pending are and were patentably distinct from the references cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations are found throughout the specification and in the originally claims as originally filed.

II. THE SECTION 102 ART REJECTIONS ARE OVERCOME

Claims 1, 7, 10-12, 16 and 30 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Kinney et al. (WO 01/60847). Claims 1-3, 7, 16 and 30 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Yamshikov et al. Claims 1, 7, 16-22 and 30 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Chan et al. (US 2003/0022849, now US Patent 7,227,011). The rejections are respectfully traversed.

It is respectfully submitted that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art

reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applicants respectfully submit that none of the cited references provide each and every element of the claims. As amended herein, the claims now require that the recombinant vector is a recombinant avipox virus. This recitation was previously present in claim 4, which claim was not subject to the Section 102 rejections.

That is, none of the cited references teach or suggest the use of a recombinant avipox virus in a vaccine composition against West Nile virus. Rather, the cited references relate to flaviviruses and vaccinia virus.

Accordingly, reconsideration and withdrawal of the Section 102 rejections is respectfully requested.

III. THE SECTION 103 ART REJECTIONS ARE OVERCOME

Claims 17 and 18 were rejected under 35 U.S.C. §103(a) as allegedly being unpatenatble over Kinney et al. Claims 10-13 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Chang. Claims 21 and 22 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined teaching of Paoletti (a) (US 5,744,141), Chang and Paoletti (b) (US 5,505,941) and further in view of Ramshaw. Claims 14 and 19 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Paoletti (a) (US 5,744,141), Chang and Paoletti (b) (US 5,505,941) and further in view of Audonnet et al. (WO 99/44633). The rejections are respectfully traversed and will be addressed collectively.

Applicants respectfully submit that the above rejections are not applicable to the pending claims. As amended herein, the claims now require that the recombinant vector is a recombinant avipox virus. This recitation was previously present in claim 4, which claim was not subject to the above-listed Section 103 rejections. Accordingly, the rejections are now moot.

Turning to the remaining Section 103 rejections, claims 1-13, 15-18 and 20 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined teaching of Paoletti (a) (US 5,744,141), Chang, and Paoletti (b) (US 5,505,941). Claims 1-11, 16-18 and 22 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, as evidenced by Paoletti (e) (US 5,756,103). Claims 1-12, 16-18 and 22 were rejected under 35 U.S.C. §103(a) as allegedly being

unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, and further in view of both Stocks and Chang. Claims 1-11, 13, 14, 16-20 and 22 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, and in further view of Mumford. Claims 1-11, 15-18 and 22 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, in further view of Varga. And, claims 1-11, 16-18, 21 and 22 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Paoletti (d) (Proc. Natl. Acad. Sci. USA 1996) in view of both Goverdhan and Ostlund, and in further view of Ruitengerg.

The Examiner is also respectfully reminded that for a Section 103 rejection to be proper, there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings to arrive at the claimed invention. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BPAI 1993). Further, the Examiner is respectfully reminded that "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification."

And, for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure**. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Examiner is also respectfully reminded that MPEP 2143.01 mandates that for a Section 103 rejection, there must be some suggestion or motivation to modify reference teachings, and, that MPEP 2143.02 further mandates that for a section 103 rejection, there must be a reasonable expectation of success. In view of *KSR*, 82 U.S.P.Q.2d 1396, design incentives and common sense may be considered sufficient motivation to combine or alter a reference, however, an obviousness rejection must still provide sufficient detail to enable an Applicant to respond.

Applicants respectfully submit that none of the references relied on in the Office Action provide any teaching or suggestion of the present invention, either individually or in any combination. Furthermore, none of the cited references provide any motivation to combine or any expectation of success. Additionally, the present invention enjoys commercial success as a

product marketed in the US, providing further evidence of the non-obviousness of the present invention.

The present invention relates in one aspect to a vaccine composition to induce a protective immune response against West Nile virus (WNV) in an animal susceptible to WNV comprising a vector comprising a recombinant avipox virus encodes and expresses *in vivo* in the animal WNV polyprotein prM-M-E.

The Office Action additionally states that the claims are rejected based on the combination of Paoletti (a) (US 5,744,141), Chang and Paoletti (b) (US 5,505,941). Applicants respectfully submit that neither Paoletti (a) or (b) teach a vaccine composition to induce a protective immune response against West Nile virus (WNV). Indeed, neither Paoletti (a) or (b) teach the use of West Nile coding sequences in an avipox virus, nor is any teaching, suggestion or motivation found in either of Paoletti (a) or (b) to modify the references to arrive at the present invention.

Specifically, Paoletti (a), the '141 patent, relates to a recombinant poxvirus having DNA which encodes protein M or prM and E of Japanese encephalitis virus, Yellow Fever virus, and Dengue virus, all of which flaviviruses. According to the Office Action, the skilled person would apply the teachings of the '141 patent to West Nile virus as allegedly described by Chang. Further, the Office Action alleges that it would have been obvious to apply the teachings of Paoletti (b) which allegedly teaches the advantages of avipox viruses for immunizing avians and mammals, especially in view of West Nile virus infecting both mammals and avians. Applicants respectfully disagree.

In contrast to the assertions of the Office Action, the very language of Paoletti (a) informs one of skill in the art that there would be no expectation of success for the combination of references suggested by the Office Action. Indeed, the '141 patent indicates that the response to recombinant vaccines comprising DNA encoding structural proteins can be unpredictable among flaviviruses. For instance, recombinant vaccines comprising DNA encoding Japanese Encephalitis Virus (JEV) structural proteins induced different responses than vaccines comprising DNA encoding Dengue type 2 structural proteins (see col. 4, lines 17-57). In fact, the vaccine comprising the Dengue type 2 structural proteins often did not induce an immunoprotective effect. Given the unpredictability among flaviviruses, and the specific requirement that the presently claimed composition provide a protective immune response (by

virture of the composition being a vaccine composition), one skilled in the art would not learn from the cited references that a recombinant vaccine comprising DNA encoding structural proteins of a flavivirus would induce protection against said flavivirus. Similarly, the skilled artisan would not presume that a recombinant vaccine comprising DNA encoding West Nile Virus prM-M-E would induce protection against West Nile Virus.

The remaining Section 103 rejections all rely on Paoletti (d) (PNAS 1996) in view of at least Goverdhan. The September 6, 2006 Office Action, which first set forth the rejections and provides the details thereof, indicates that Paoletti (d) relates to a method of inducing an immunological response against Japanese encephalitis virus (JEV) by administering to a subject an immunogenic composition comprising NYVAC and ALVAC encoding for the polyprotein PrM/M, E of JEV. Applicants first note that in actuality, the reference refers to NYVAC encoding for PrM/M, E **and NS1** of JEV. There is nothing in Paoletti (d) that would lead one of skill in the art to select PrM/M and E from this recombinant vector. Further, NYVAC is a vaccinia virus, not an avipox virus as is required by the pending claims.

As mentioned above, the September 6, 2006 Office Action alleged (which rejection has been maintained in the present Office Action) that Paoletti (d) also refers to the use of a canarypox vector which the Office Action presumes to be ALVAC, and implies that the ALVAC encodes the same proteins as the NYVAC vector described on page 11351, column 2, bridging p. 11352, col. 1. This is not correct. Rather, Paoletti (d) indicates that "a canarypox-based Japanese encephalitis recombinant are currently being evaluated in human clinical trials." However, **no** information regarding that canarypox-based recombinant is actually provided by the reference. From a thorough reading of the reference, one of skill in the art can make no assumptions as to the composition of the referred-to canarypox recombinant.

Furthermore, as discussed above, Paoletti's own work, contemporaneous to the PNAS article, has refuted the ability to interchange flaviviruses with predictable results. Again, the '141 patent indicates that the response to recombinant vaccines comprising DNA encoding structural proteins can be unpredictable among flaviviruses and provides evidence of such unpredictability in the form of differing responses obtained with recombinant vaccines comprising DNA encoding JEV structural proteins versus Dengue type 2 structural proteins (see col. 4, lines 17-57). In fact, the vaccine comprising the Dengue type 2 structural proteins often did not induce an immunoprotective effect. Therefore, Applicants again submit that given the

unpredictability among flaviviruses, and the specific requirement that the presently claimed composition provide a protective immune response, one skilled in the art would not learn from the cited references that a recombinant vaccine comprising DNA encoding structural proteins of a flavivirus would induce protection against said flavivirus. Similarly, the skilled artisan would not presume that a recombinant vaccine comprising DNA encoding West Nile Virus prM-M-E would induce protection against West Nile Virus.

None of the additionally cited references overcome these deficiencies.

Goverdhan is relied upon by the Office to teach that immunization with JEV protects against West Nile, and therefore it would be obvious to develop a vaccine against WNV according to the teachings of Paoletti by replacing the JEV prM/M, E with the WNV prM/M, E, with a reasonable expectation of success. Applicants disagree.

Although Goverdhan demonstrated some cross response between JEV and WNV, WNV vaccine utilized in Goverdhan was significantly less protective than was the JEV vaccine. This teaches one of skill in the art that the JEV and WNV are not fully interchangeable with predictable results. Indeed, the WNV vaccine resulted only in a reduction of the severity of the disease following challenge with JEV (see abstract), a far cry from being able to expect a comparable protective response. Furthermore, Goverdhan relied upon formalin-killed vaccines. Given Paoletti's own teachings in the '141 patent that the immune response to recombinant vaccines comprising DNA encoding structural proteins can be unpredictable among flaviviruses, one of skill in the art would not assume a likelihood of success from (1) taking the formalin-killed WNV vaccine of Goverdhan, which only led to a reduction in symptom severity and (2) selecting specific proteins of WNV to be expressed in an avipox virus, knowing that such recombinant virus expression does not have predictable results among flaviviruses, and (3) expect to obtain a protective response. To suggest otherwise is to discount the teachings in the art at the time of filing, including the other works of Paoletti.

Accordingly, the combination of Paoletti (d), Goverdhan and Ostlund does not teach or suggest the present invention, nor is there any motivation to combine or suggestion of success in so doing. As all of the remaining art rejections initially turn on the combination of these three documents, and as none of the remaining cited documents address the deficiencies described above, all of the rejections under §103 fail and must be withdrawn.

Furthermore, Applicants respectfully submit that the present invention provides surprising and unexpected results that enjoy real world success, and that such real world success is commensurate in scope with the pending claims that relate to a recombinant avipox. The Examiner is again respectfully invited to review Example 32 of the present application wherein one dose efficacy of a canarypox vectored West Nile Virus vaccine (vCP2017) against a WNV-infected mosquito challenge in horses was described, wherein 1/9 vaccinated horses developed detectable West Nile virus viremia (11.1%), whereas 8/10 control horses (unvaccinated) developed detectable viremia (80%) post challenge. Furthermore, Applicants have submitted herewith as Exhibit A an advertisement for a commercially available product marketed by the Assignee of the present application and which is encompassed by the pending claims. If necessary, Applicants can submit such evidence in the form of a declaration.

For all of the reasons described above, the art rejections are improper and must be withdrawn, specifically as the references cited are unavailable and/or fail to teach or suggest the present invention. Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. § and 103 are respectfully requested.

III. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME

Claims 1-22 and 30 were provisionally rejected on the basis of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-30 of copending Application No. 10/679,520. The rejection is respectfully traversed. Applicants thank the Examiner for acknowledging that Applicatns will address this rejection upon a determination of allowable subject matter in either the present application or USSN 10/679,520.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, a further interview, is respectfully requested, with the Examiner and her supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks made herewith, the application is in condition for allowance. Favorable reconsideration of the application, and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: /Angela M. Collison/
Thomas J. Kowalski
Reg. No. 32,147
Angela M. Collison
Reg. No. 51,107
Tel (212) 588-0800